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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,560	01/17/2001	Robert Wayne Glenn JR.	8392	6902

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,560

Applicant(s)

GLENN ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of Information Disclosure Statement dated 4-11-02 and amendment A, dated 4-23-02 is acknowledged.

Status of Claims

Claim 22 has been amended and new claims 26-30 have been added. Accordingly, claims 1-30 are pending.

Response to Arguments

Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

1. Claim 18 recites the limitation "phospholipids" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 17, further limits claim 16 and recites that the surfactant comprises quaternary ammonium halides and cholesterol. However, claim 18, which is dependent upon claim 17, recites that the surfactant is a phospholipids. Claim 17 does not require phospholipids nor does it recites surfactants in general. Accordingly, it appears that claim 18 should be dependent upon claim 16 and not claim 17.

2. Claim 19 recites the limitation "quaternary ammonium halides and nonionic surfactant" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Claim 18 is only limited to phospholipids surfactants. It appears that the claim 19 should be dependent upon claim 16 instead.

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Appropriate correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8 and 11-21 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,362,494 to Zysman et al (hereafter Zysman).

Zysman teaches cosmetic, dermo-pharmaceutical compositions containing non-ionic and ionic amphiphilic surfactants, which form vesicles. Zysman teaches oil-in-water and water-in-oil compositions in which the amphiphilic surfactants are employed along with other surfactants (col. 3, lines 53-65). The amphiphilic surfactants of Zysman include natural and synthetic phospholipids (col. 5, lines 26-37). Zysman teaches that the vesicles are dispersed in an aqueous phase, which contains water immiscible solvents to stabilize vesicles, which include oils, hydrocarbon compounds, silicones etc (col. 12, lines 25-57). Further, the water immiscible solvent contains lipophilic active substances, which read on the instant reactive components. The surfactants of instant claim 1 read on the amphiphilic lipids of Zysman and the dispersion of vesicles in the aqueous phase (taught by Zysman) is nothing but a bi-layer emulsion, as claimed.

Zysman teaches addition of active agents in the composition to either encapsulated water phase or continuous water phase or the lipid phase, depending on the solubility of the active agent used and further suggests a number of skin and hair care active agents (col. 7, lines 28-60) and in particular, compounds that are suitable for treating hair loss, for hair dyes, bleaching and

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permanent waving of hair (such as N-acetylcysteamine) (col. 11, lines 50-68). Examiner notes that N-acetylcysteamine of Zysman read on the instant reactive component (claim 1) and in particular, nucleophilic reactive group (claim 8). Further, N-acetylcysteamine also meets the requirement of being covalently reactive with an amino acid based substrate because instant specification describes cysteamine derivatives as reactive component and hair keratin as an amino acid base.

With respect to instant combination of cholesterol and quaternary ammonium surfactants, Zysman teaches addition of one more charged lipid to the amphiphilic lipids such as sterols (e.g., cholesterol), quaternary ammonium derivatives etc (col. 7, lines 5-27), so as to impart stability to the vesicles by preventing their flocculation and fusion, as well as increase their encapsulation. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate additional surfactants such as cholesterol or quaternary ammonium compounds in the composition containing aqueous dispersion of vesicles of Zysman because Zysman suggests that the additional charged lipids decrease vesicle permeability, increase their stability, prevent flocculation of the vesicles and finally enhance the encapsulation. With respect to the percentages and ratios of surfactants, Zysman teaches 0.5 to 50% vesicle forming lipids. Further, optimizing the amounts of solvents, active substances and additional lipids such as cholesterol with an expectation to deliver the active substances to the intended site would have been obvious for one of an ordinary skill in the art.

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4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,362,494 to Zysman et al (hereafter Zysman) as applied to claims 1-6, 8, 11-21 and 24-30 above, and further in view of US 5,525,332 to Gough et al (hereafter Gough).

Zysman fails to teach a reactive agent comprising the claimed electrophilic group in the composition containing aqueous dispersion of lipid vesicles. Zysman suggests incorporating hair-conditioning polymers in the composition.

Gough teaches hair-conditioning composition containing vinyl azolactone and methacryloyl polydimethylsiloxane polymer for imparting conditioning benefit to hair and for improved retention of the conditioning agent for a long time on the hair. The polysiloxane polymer is functionalized with azolactone such that the electrophilic reactive component of azolactone reacts with the nucleophilic reactive sites on the surface of the substrate i.e., hair or keratin fibers (col. 3, col. 4 and col. 7, lines 25-38). Gough also teaches various polymeric materials that can be functionalized with azlactone (col. 6). Further, Gough suggests that the azlactone functionalized materials may be soluble or dispersible in organic solvents such as silicones, hydrocarbons etc., and can be used in solutions or emulsions (col. 7, lines 49-68 and col. 8, lines 1-9). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate the azolactone functionalized polymers or other cosmetic agents functionalized with azolactone in the aqueous dispersion of Zysman containing amphiphilic lipids in combination with other charged lipids such as cholesterol because Gough teaches that the hair conditioning compounds containing azolactone functionalized polymers are useful in achieving a greater degree of chemical bonding of the cosmetic agent with the substrate

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due to the electrophilic nature and thus achieve an enhanced degree of hair conditioning and styling for long time (col. 7, lines 25-49).

5. Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,362,494 to Zysman et al (hereafter Zysman) as applied to claims 1-6, 8, 11-21 and 24-30 above, and further in view of US 5,087,733 to Deppert et al (hereafter Deppert).

Zysman fails to teach the claimed reactive compounds containing a nucleophilic reactive group, in particular, thiol groups. However, Zysman suggests incorporating hair-conditioning agents in the aqueous dispersions containing amphiphilic vesicles.

Deppert teaches hair-conditioning compositions containing sulfur containing quaternary ammonium compounds such as sulfhydryl, dithio, isothiuronium compounds that react with the anionic charge carried on the keratin of human hair fibers. In particular, after treating with thioglycolic acid (for permanent waving of hair), free mercaptan groups formed due to reduction of thioglycolic acid are remained on the hair fibers. The thiol containing quaternary compounds of Deppert reacts covalently with the free mercaptan groups, thus binding the conditioner to the hair for a longer period of time (col. 8, lines 8-20). Further, Deppert suggest water immiscible solvents such a benzyl alcohol for stabilizing the sulfur containing compounds. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate the sulfur containing quaternary ammonium compounds such as disulfhydryl, dithiol or diisothiouranium containing quaternary ammonium conditioners of Deppert in the aqueous dispersions containing amphiphilic vesicles of Zysman because the sulfur containing

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hair conditioners of Deppert interact with the anionic charge of human hair very efficiently i.e., each molecule forms two covalent bonds with sulfhydryl radicals on hair 9col. 9, lines 58-64) and thus bind to the hair through several shampoos (i.e., long lasting effect) (col.1, lines 62-68).

Examiner notes that the co-pending application No. 09/478,855 has been printed wrong on page 7 of the specification. Further, instant claim 8 has recited thiosulfate twice. It is suggested that these typographical mistakes are corrected. Further, it is also requested that applicants update the status of the co-pending applications in the instant specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615

July 11, 2002